UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,435	03/29/2001	Michael Clare-Salzer	UF-160CD2	1769

23557 7590 05/13/2003

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/13/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
821,435	CLARE-SALZLER
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 9/3/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-9 is/are pending in the application.

Of the above claim(s)_____ is/are withdrawn from consideration.

☐ Claim(s)_____ is/are allowed.

☑ Claim(s) 1-3, 6-9 is/are rejected.

☑ Claim(s) 4 is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other_____

Office Action Summary

Claims 1-9 are pending.

Applicant's response filed on 2/3/03 has elected TGF-beta as the species of PGS-2 inhibitor.

Claims 1-2 and 6-9 read on the elected species.

Claims 3-5 will be examined for prior art to the extent that there claims are found to be anticipated/obvious over prior art found in searching for the elected species or for the genus, or in reviewing references of the IDS.

Claims 1-2 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of the genus of compounds which serve as "prostaglandin inhibitors", including those that "decrease production or block the activity of PGS-2".

Applicant's disclosure and claims merely represent a wish for a described, desirable end result, but has not adequately described what compounds constitute members of the genus, so that one would recognize whether or not a particular compound belongs to the genus.

Beyond specific teachings of NS-398, indomethacin, IL-4, IL-10, IL-13 and TGF-B, applicant has given no direction as to what compounds to use. They are not representative of the genus because they have diverse structures and diverse biological activities. See "Dictionary of Cytokines" for entries describing the biological activities of these interleukins and TGF-B. None

of these entries mention anything about the inhibition of PGS-2 activity. The reader has no idea from the disclosure as to what kind of screening assay, if any, lead applicant to conclude that these cytokines should be listed as useable in the claimed method. Irrespective of whether or not there has been a description of an appropriate screening method is immaterial, for such would merely set forth a research plan for someone else to arrive at the compounds that one would need to practice the invention; a description of a screening method is not a description of the compounds which might be found by such method.

Claims 1-2 and 6-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for use of the PGS-2 inhibitors NS-398, indomethacin, IL-4, IL-10, IL-13 and TGF-B, does not reasonably provide enablement for the use of any prostaglandin inhibitors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Undue experimentation would be required to arrive at the compounds required to practice the claimed treatment method.

Even if applicant has provided adequate direction as to how to conduct screening assays so that one can identify such compounds, such direction would not provide the necessary link between the steps of screening and practicing the claimed method of treating that actually works. Except for the particular compounds listed, the disclosure provides little guidance in the way of selecting a particular compound that is suitable, without need for undue trial and error experimentation.

Regarding 112, first issues applicant is referred to Science, 299, 1638-1639, 2003 and to the link to the decision cited therein.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Reder et al. (J. Neuroimmunol. 54, 117-127, 1994), cited in IDS.

Reder et al. show that indomethacin (a PGS-2 inhibitor according to applicant's own disclosure) inhibits the development of EAE (Fig. 1), which is an autoimmune disease. Since indomethacin was administered along with the antigens inducing EAE (p. 118, col. 2), the limits of claim 6 are met. claim 9 is considered inherently anticipated, since applicant's own disclosure indicates that IL-1Ra elevation is a result of administering PGS-2 inhibitors.

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Secchi et al. (Transpl. Proceed. XVIII, 1540-1542, 1986).

Secchi et al. show that indomethacin administration induces remission in recent onset IDD patients. Since these patients were treated with insulin (see materials and methods), claims 6 and 8 are anticipated. Claim 9 is rejected following the rational stated supra.

Claims 1-2, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Kuruvilla et al., Racke et al. or Johns et al., (cited on 892) in light of Wahl (J. Clin. Immunol, 12, 61, 1992, cited in IDS).

Each reference shows the use of TGF-B for prevention or treatment of EAE, an autoimmune disease. Claim 6 is rejected,

following the rational stated for Reder et al. claim 9 is rejected, since Wahl teaches that TGF-B can induce IL-1Ra synthesis (p. 67, col. 1).

Claims 1-2, 7 and 9 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Bond et al. (WO 94/08606 or U.S. 5,827,513) in light of Howard et al. (cited in IDS).

The WO and U.S. references have equivalent disclosures. For convenience, the examiner will refer to col. and line nos. of the U.S. reference.

Bond et al. teach and claim the treatment of individuals predisposed to diabetes via the administration of IL-10. While they do not disclose an effect of IL-10 upon PGS-2; it is considered that IL-10 would inherently act as a PGS-2 inhibitor when administered in accord with the teachings of Bond et al. Evidence in support of this assertion is applicant's own statement (para. Spanning pages 7-8) that the inhibitors of PGS-2 which can be administered according to the invention include IL-10. Mere statement of a mechanism by which a known agent may act cannot impart patentability, when using the agent for the same goal is known.

Claim 9 is rejected since Howard et al. teach (page 242) that IL-10 has the inherent property of up regulating IL-1Ra.

Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lernmark et al. (WO 92/20811) in view of Bond et al.

Lernmark et al. teach that it is known to administer GAD polypeptide autoantigen in order to induce tolerance in patients susceptible to IDDD. They teach that the autoantigen may be co-administered with an immunosuppressive drug. See pages 20-21, especially first full paragraph of page 24.

Bond et al. have been noted supra in the rejection of the base claim for teaching the administration of IL-10 to individuals predisposed to diabetes, and the examiner has indicated the instantly recited mechanism of action does not impart patentability. Since Bond et al. teach that their disclosed treatment with IL-10 has advantages over conventional treatments with immunosuppressive drugs (col. 2, lines 27-49 and col. 6, 58-65), it would have been obvious to administer IL-10 in lieu of or along with reduced amounts of the immunosuppressive drugs taught by Lernmark et al. as being suitable for co-administration with the autoantigen.

Claims 1-2 and 9 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Ducharme et al. (U.S. 5,474,995 or WO95/18799).

The U.S. and WO references have the same disclosure.

Ducharme et al. teach administration of compounds which inhibit COX-2/PGS-2. This patent covers the inhibitor currently marketed as VIOXX. Among the diseases listed as treatable are autoimmune diseases such as rheumatoid arthritis, ankylosying spondylitis, ulcerative colitis (e.g. col. 7, lines 37-38 and 57). Claim 9 is included since the administration of a PGS-2 inhibitor is deemed to increase the production of IL-1RA as a natural and inherent consequence of such administration whether or not this was realized by the prior art.

Claims 1-2, 7 and 9 are rejected under 35 U.S.C. 102(a) or(b) as being anticipated by Talley et al. (U.S. 5,466,823 or WO 95/15316).

The U.S. and WO references have the same disclosure. Talley et al. teach administration of a COX-2/PGS-2 inhibiting compound. This patent covers the inhibitor currently marketed as CELEBREX. Among the diseases listed as being treatable are numerous autoimmune diseases, including type I diabetes. See col. 3, lines 1-26. Claim 9 is included for reasons stated supra.

See Merck Index for correlation of the Ducharme et al. and Talley et al. disclosures with tradenames.

Claims 1-3, 5 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al. (6,048,850).

Young et al. teach treatment of various diseases with PGHS-2/PGS-2 inhibitors. These disease include multiple sclerosis (col. 28, line 29), which is an autoimmune disease. They teach indomethacin as an inhibitor (sections 7.2.4 and 10). Also, they teach NS-398 as an inhibitor (col. 28, lines 38-40).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 6-9 are ejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. No. 6,168,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and issued claims encompass common subject matter.

Both sets of claims administer a PGS-2 inhibitor for the purpose of inhibiting the development of an autoimmune disease (instantly claimed as a generic such disease and, as issued, claimed specifically as IDD). Instant claim 9 is included since the recited result of "increasing the production of IL-1RA" is taken to occur as a natural consequence of administering a PGS-2 inhibitor. A disclaimer is required to assure that any patent issued instantly would remain in common ownership with the `792 patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 6, 2003

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644